

**REMARKS**

The Office Action mailed September 19, 2006 has been received and reviewed. Claims 1-26 are pending in the application. Claims 1-19 are currently under examination. All stand rejected. Reconsideration is respectfully requested.

1. Priority

Applicants thank the Examiner for acknowledging the priority claim. Applicants note that in the parent application, US Application No. 09/716,612, filed November 20, 2000, the Office acknowledged on a PTO-326 mailed November 27, 2002 receipt of copies of certified copies of the priority documents from the International Bureau. A copy of the PTO-326 is enclosed. Therefore, pursuant to M.P.E.P. § 201.14(b)(II) a certified copy need not be filed in this application. If the document is no longer available at the Office, the Examiner is kindly requested to contact applicants' representative, and a certified copy will be promptly provided as a courtesy.

2. Claims 1-3 and 5-19 and 35 U.S.C. § 102(b)

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by US 4,906,457 (hereinafter "Ryan") in the light of evidence by Pearce *et al.* (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462) (hereinafter "Pearce"). Specifically, it was thought that Ryan discloses a skin care or topical pharmaceutical composition comprising an inhibitor of proteolytic activity that is derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Applicants respectfully traverse the rejections.

As already argued in applicants' previous response, Ryan does not disclose a combination of proteases from potato where said combination is formed by a trypsin inhibitor and an elastase inhibitor. Rather, Ryan discloses, at best, a combination of a potato chymotrypsin or trypsin inhibitor and an elastase inhibitor from an unknown source. This is further exemplified in Example 3, where the elastase inhibitor is disclosed as from a commercially available source. The Examiner points to Pearce to demonstrate that inherently the potato enzymes chosen by Ryan also would have an elastase-inhibiting effect. However, applicants respectfully submit that

the Examiner is inappropriately applying the disclosure of Pearce. Pearce only discloses that two specific chymotrypsine-type inhibitors from potato also have an elastase-inhibiting effect, while the trypsin inhibitor (indicated as PTI) was shown to only have a weak inhibitory effect. *Pearce, page 461*. Ryan does not disclose the same two specific chymotrypsine-type inhibitors as disclosed in Pearce. Therefore, it cannot be inherent that the chymotrypsine inhibitors of Ryan would have elastase-inhibiting effect.

Furthermore, there have also been studies by Revina *et al.*, 1995, Valueva *et al.*, 1997, and Valueva *et al.*, 2000, abstracts enclosed, of which the first abstract discloses a trypsin and chymotrypsin inhibitor isolated from potato, which does not show an inhibitory effect on elastase. The second abstract discloses an elastase and trypsin inhibitor from potato which only has limited chymotrypsin inhibiting effects. The third report discloses an elastase inhibitor from potato with marginal effects on trypsin and chymotrypsin. More recently, the same group (Speranskaya *et al.*, 2006, abstract enclosed) published data on a further potato protease inhibitor, which inhibits trypsin and to a lesser extent chymotrypsin, and has no effect on elastase. These studies illustrate that not all trypsin and chymotrypsin inhibitors isolated from potatoes have elastase-inhibiting effect. Therefore, one of skill in the art would not recognize that the chymotrypsin and trypsin inhibitors of Ryan “necessarily” described an elastase inhibitor as required to establish inherency. *See M.P.E.P. § 2112*.

To further stress the argument that a person skilled in the art would not automatically consider all potato protease inhibitors (and especially those shown by Ryan) to also exert elastase inhibiting characteristics, Table 2 from the dissertation of L. Pouvreau (2004) is enclosed. In the table, the inhibitory effects of potato proteases as reported in the literature are listed. Remarkably, in only one group of protease inhibitors is an elastase inhibiting effect mentioned. Thus, a person skilled in the art on the basis of the disclosure of Ryan would not come to the conclusion that the disclosure of chymotrypsin and trypsin inhibitor from potato in Ryan would automatically have elastase-inhibiting effects.

If it were known that potatoes automatically have elastase-inhibiting effects, then Ryan would not need to have suggested that elastase inhibitors are “[a]lso appropriate.” *See column 2, line 6*. Rather, Ryan would have included the elastase inhibitors in the discussion of inhibitors derived from potatoes. This is especially the case since Ryan was co-author in Pearce. If Pearce

evidenced that all chymotrypsine and trypsin inhibitors in potatoes were also elastase inhibitors, then Ryan would be aware of it.

Furthermore, the elastase inhibitors mentioned in Ryan are not disclosed as obtainable from potatoes, but rather are disclosed as “commercially available.” *Column 2, line 11; column 4, line 44.* At the time of filing (and still now) the elastase inhibitors which are commercially available are of human (or mammalian) origin, and not from potato origin.

It is therefore submitted that Ryan does not inherently describe the potato-derived composition of the claimed invention, nor that it is obvious from the combination of Ryan and Pearce, since Pearce is not conclusive and there are contradictory statements in the literature.

Therefore, for at least the above reasons, Ryan in light of evidence by Pearce cannot anticipate claim 1. Claims 2, 3, and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

### 3. Claims 1-3 and 5-19 and 35 U.S.C. § 102(b)

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by US 3,950,509 (hereinafter “Geks”) in the light of evidence by Pearce. Specifically, it was thought that Geks discloses a skin care or topical pharmaceutical composition comprising a cosmetically or pharmaceutically acceptable vehicle and a proteolytic activity inhibitor derived from potato that includes kallikrein-trypsin inhibitor derived from potatoes. Applicants respectfully traverse the rejections.

A similar reasoning applies to Geks as discussed above regarding Ryan. Although Geks could be said to disclose the use of more than one inhibitor from potato, the examples only show use of one inhibitor (*e.g.*, by using the words the vegetable protease inhibitor). For the potato inhibitor, Geks refers to Balls and Ryan (1963). *Column 2, lines 3-4.* Applicants submit that Balls and Ryan (1963) is dealing with a chymotrypsin inhibitor. The same arguments with respect to Ryan and Pearce are applicable to Geks and Pearce. One of skill in the art would not recognize Pearce as describing that all protease inhibitors from potatoes are necessarily also elastase inhibitors. Thus, the protease inhibitors of Geks would not necessarily describe elastase inhibitors. Thus, Geks does not inherently describe the potato-derived composition of the

claimed invention, nor would the combination of Geks and Pearce make the claimed invention obvious.

Therefore, for at least the above reasons, Geks cannot anticipate claim 1. Claims 2, 3, and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

4. Claims 1, 2, 4-6, 12, and 13 and 35 U.S.C. § 102(b)

Claims 1, 2, 4-6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Rodis *et al.*, ("Naturally occurring protein crystals in the potato." Plant Physiol. 1984, 74:907-911) (hereinafter "Rodis") in the light of evidence by Pearce. Specifically, it was thought that Rodis discloses a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle such as sodium acetate buffer. Applicants respectfully traverse the rejections.

Rodis is the reference which is farthest away from the present invention, since it does not disclose any cosmetic composition as such. Rodis merely discloses that the protein inhibitor is soluble in sodium acetate buffers, which indeed can be regarded as a buffer which is of use in cosmetic applications. Rodis does not expressly or inherently describe the claimed invention. Rodis does not describe a composition of more than one potato protease inhibitor. Additionally, Rodis does not disclose that the inhibitor which is analyzed shows elastase-inhibiting characteristics. For the reasons discussed above, one of skill in the art would not recognize Pearce as describing that all protease inhibitors from potatoes are necessarily also elastase inhibitors. Thus, the protease inhibitor of Rodis would not necessarily describe an elastase inhibitor. Further, it follows from Table 2 of Pouvreau (2004) that potato protease inhibitors which are effective against papaine do not have elastase inhibiting properties. Thus, Rodis does not inherently describe the potato-derived composition of the claimed invention, nor can a combination of Rodis and Pearce make the claimed invention obvious.

Therefore, for at least the above reasons, Rodis cannot anticipate claim 1. Claims 2, 4-6, 12, and 13 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

5. Claims 1-19 and 35 U.S.C. § 103(a)

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Ryan and Geks taken with Rodis and Pearce. Specifically, it was thought that Ryan and Geks are silent about the pH of compositions with potato inhibitors. It was suggested that Rodis teaches that potato protease inhibitors are readily dissolved at pH 4-5 unlike neutral or alkaline pH. Applicants respectfully traverse the rejections.

For at least the reasons discussed above, none of the cited references alone or in combination teach or suggest “a skin care or topical pharmaceutical composition comprising at least a combination of a trypsin inhibitor and an elastase inhibitor and a cosmetically or pharmaceutically acceptable vehicle, and wherein the inhibitors are derived from potato.” Therefore, claim 1 is non-obvious and claims 2-19 are non-obvious for depending therefrom. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

6. Supplemental Information Disclosure Statement (hereinafter “SIDS”)

Revina *et al.*, 1995; Valueva *et al.*, 1997; Valueva *et al.*, 2000; Speranskaya *et al.*, 2006; and Table 2 of Pouvreau, 2004 have been listed on an SIDS filed herewith. Applicants submit that the SIDS complies with 37 C.F.R. § 1.97(d). The references were not deemed potentially material to patentability until the recent reliance by the Examiner on Pearce. Thus, applicants have not known of the potential materiality of the documents for more than three months. *See* 37 C.F.R. 1.97(e)(2). Additionally, the required fee is enclosed.

In the event that the Office determines that the SIDS is not considerable, applicants respectfully submit that the references qualify as “other evidence” under 37 C.F.R. § 1.116(e). Applicants submit that the “good and sufficient reason” for why the references were not presented earlier is that applicants did not realize the necessity of presenting the documents until the recent rejections by the Office relied upon Pearce.

Additionally, should the Office determine that a fee is not required, the Office is kindly requested to credit TraskBritt deposit account no. 20-1469.

**Serial No. 10/727,345**

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

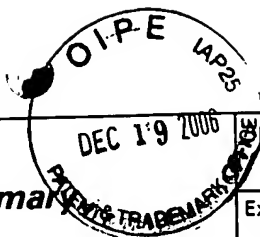
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Date: December 19, 2006

Enclosures: PTO-326 from parent application  
Supplemental IDS



# Office Action Summary

Application No.  
09/716,612

Applicant(s)

Geertruida et al.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 11, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 8-14, 19, 20, 24, 25, 29, and 32-35 is/are pending in the application.
- 4a) Of the above, claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8, 9, 11-14, 19, 20, 24, 25, 29, and 32-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_